

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Gantier *et al.*
Serial No.: 10/658,355
Filed : September 08, 2003
Cust. No.: 24961
Conf. No.: 3519
For: **RATIONAL DIRECTED PROTEIN
EVOLUTION USING TWO-
DIMENSIONAL RATIONAL
MUTAGENESIS SCANNING**
Art Unit: 1645
Examiner: Unassigned



TRANSMITTAL LETTER

Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith via hand delivery are an Information Disclosure Statement, Form PTO-1449 (8 pages), and cited references for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed prior to receipt of a First Office Action on the merits in the above-identified application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:

(X) The Commissioner is hereby authorized to charge any fees that may be due under 37 C.F.R. §§1.16-1.17 in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

By: 
Stephanie L. Seidman
Registration No. 33,779

Dated: March 17, 2004
Attorney Docket No. 37851-0922
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INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE
WITH 37 C.F.R. §§ 1.97-1.98

Commissioner for Patents
U.S. Patent and Trademark Office
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Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is filed prior to receipt of a First Office Action on the merits of the above-captioned application. Thus, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (8 pages) and copies of the cited documents are provided herewith in connection with the above-captioned application.

The documents listed on Form PTO-1449 and supplied herewith are all in the English language with the exception of items K, L, P, and Q. Patent numbers WO 01/44809 (item K), WO 01/86291 (item L), FR 2802645 (item P)

U.S.S.N. 10/658,355**Gantier *et al.*****Information Disclosure Statement**

and FR 2808804 (item Q), are in the French language and supplied with English language equivalents (item No. B for items K and P, and item No. D for items L and Q) describing the subject matter. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following U.S. and International applications, which are commonly owned and/or have one or more inventors in common:

| <u>U.S.S.N.</u> | <u>Filing Date</u> | <u>Publ'n. No.</u> | <u>Publ'n. Date</u> | <u>Docket No.</u> |
|-----------------|--------------------|--------------------|---------------------|-------------------|
| 10/022,249 | 12/17/01 | 2003-0134351 | 07/17/03 | 911 |
| 10/022,390 | 12/17/01 | 2003-0129203 | 07/10/03 | 912 |
| 10/375,192 | 02/24/03 | 2003-0224404 | 12/04/03 | 918 |
| 60/457,135 | 03/21/03 | | | P922B |
| 10/658,834 | 09/08/03 | | | 922 |
| 60/457,063 | 03/21/03 | | | P923B |
| 10/168,075 | 10/28/02 | 2003-0129584 | 07/10/03 | N/A |
| 10/275,253 | 05/09/03 | 2003-0175694 | 09/18/03 | N/A |

| <u>Int'l App. No.</u> | <u>Filing Date</u> | <u>Publ'n No.</u> | <u>Docket No.</u> |
|-----------------------|--------------------|-------------------|-------------------|
| WO 2003023032 | 08/16/02 | PCT/IB02/03921 | 911PC |
| WO 200318820 | 08/16/02 | PCT/IB02/04087 | 912PC |
| Unassigned | 09/09/03 | | 922PC |
| Unassigned | 09/09/03 | | 923PC |
| EP1281081 | 05/04/01 | | N/A |
| EP1244912 | 12/13/00 | | N/A |
| WO 0186291 | 05/04/01 | | N/A |
| WO 010144809 | 12/13/00 | | N/A |

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

U.S.S.N. 10/658,355

Gantier *et al.*

Information Disclosure Statement

Applicant respectfully requests that the Examiner review the foregoing references and information and that they be made of record in the file history of the above-captioned application.

Respectfully submitted,

By:


Stephanie L. Seidman
Registration No. 33,779

Dated: March 17, 2004

Attorney Docket No. 37851-0922

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|--|----------------------------------|--------------------------|---------------------|
| FORM PTO-1449 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT | ATTY. DOCKET NO. 37851-923 | SERIAL NO. 10/658,355 | CONFIRM NO. 3519 |
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U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | *Ref. Code | DOCUMENT NUMBER | | | | | | | DATE | NAME | CLASS | SUB CLASS | FILING DATE |
|---------------------|---------------|-----------------|---|---|---|---|---|---|----------|-----------------|-------|--------------|----------------|
| | A | 0 | 1 | 2 | 9 | 2 | 0 | 3 | 07/10/03 | Vega et al. | 424 | 233.1 | 12/17/01 |
| | B | 0 | 1 | 2 | 9 | 5 | 8 | 4 | 07/10/03 | Vega | 435 | 5 | 12/13/00 |
| | C | 0 | 1 | 3 | 4 | 3 | 5 | 1 | 07/17/03 | Vega et al. | 435 | 69.1 | 12/17/01 |
| | D | 0 | 1 | 7 | 5 | 6 | 9 | 4 | 09/18/03 | Vega | 435 | 5 | 05/04/01 |
| | E | 0 | 2 | 2 | 4 | 4 | 0 | 4 | 12/04/03 | Vega et al. | 435 | 6 | 02/24/03 |
| | F | 4 | 0 | 4 | 4 | 1 | 2 | 6 | 08/23/77 | Cook et al. | 424 | 243 | 07/09/76 |
| | G | 4 | 3 | 6 | 4 | 9 | 2 | 3 | 12/21/82 | Cook et al. | 424 | 46 | 04/30/81 |
| | H | 4 | 4 | 1 | 4 | 2 | 0 | 9 | 11/08/83 | Cook et al. | 424 | 243 | 06/13/77 |
| | I | 4 | 5 | 2 | 2 | 8 | 1 | 1 | 06/11/85 | Eppstein et al. | 514 | 2 | 07/08/82 |

FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL | *Ref. Code | DOCUMENT NUMBER | | | | | | | DATE | COUNTRY | CLASS | SUB CLASS | Translation Yes No | |
|---------------------|---|-----------------|---|---|---|---|---|---|-------------|---------|-------|--------------|-----------------------|----|
| | J | 0 | 1 | 3 | 2 | 7 | 1 | 1 | A2 05/10/01 | PCT | | | | |
| | K | 0 | 1 | 4 | 4 | 8 | 0 | 9 | A2 06/21/01 | PCT | | | | X+ |
| | L | 0 | 1 | 8 | 6 | 2 | 9 | 1 | A1 11/15/01 | PCT | | | | X+ |
| | M | 03 | 0 | 2 | 3 | 0 | 3 | 2 | A2 03/20/03 | PCT | | | | |
| | N | 03 | 0 | 1 | 8 | 8 | 2 | 0 | A2 03/06/03 | PCT | | | | |
| |  | 1 | 0 | 2 | 2 | 3 | 3 | 5 | 07/26/00 | EP | | | | |

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Title: **RATIONAL DIRECTED PROTEIN EVOLUTION USING TWO-DIMENSIONAL RATIONAL MUTAGENESIS SCANNING**

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|---------------------|---------------|-----------------|---|---|---|---|---|---|-------------|---------|-------|--------------|-----------------------|----|
| | P | 2 | 8 | 0 | 2 | 6 | 4 | 5 | A1 06/22/01 | FR | | | | X+ |
| | Q | 2 | 8 | 0 | 8 | 8 | 0 | 4 | A1 11/16/01 | FR | | | | X+ |
| | R | 9 | 7 | 3 | 8 | 7 | 2 | 3 | 10/23/97 | PCT | | | | |
| | S | 9 | 8 | 3 | 2 | 8 | 8 | 0 | 07/30/98 | PCT | | | | |
| | T | 9 | 8 | 3 | 2 | 8 | 9 | 0 | 07/30/98 | PCT | | | | |

X+ = An English Language Equivalent is provided.

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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|---|---|
| U | Astwood <i>et al.</i> , "Stability of food allergens to digestion in vitro", <i>Nature Biotechnology</i> , <u>14</u> :1269-1273 (1996) |
| V | Bellido <i>et al.</i> , "The phospholipid and fatty acid composition of skeletal muscle cells during culture in the presence of vitamin D-3 metabolites," <i>Biochim Biophys Acta</i> , <u>922(2)</u> :162-169 (1987) |
| W | Bernkop-Schnurch, A. "The use of inhibitory agents to overcome the enzymatic barrier to perorally administered therapeutic peptides and proteins", <i>Journal of Controlled Release</i> , <u>52</u> :1-16 (1998) |
| X | Biron <i>et al.</i> , "Natural Killer Cells In Antiviral Defenses: Function and Regulation by Innate Cytokines," <i>Annu. Rev. Immunol.</i> , <u>17</u> :189-220 (1999) |
| Y | Boger <i>et al.</i> , "Surface Probability Profiles. A Heuristic Approach to the Selection of Synthetic Peptide Antigens," <i>Reports of the Sixth International Congress in Immunology</i> , p. 250 (1986) |
| Z | Briand <i>et al.</i> , "Impact of the lysine-188 and aspartic acid-189 inversion on activity of trypsin," <i>FEBS Lett.</i> , <u>442(1)</u> :43-47 (1999) |

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| | |
|----|---|
| AA | Cockburn, A. "Assuring the safety of genetically modified (GM) foods: the importance of an holistic, integrative approach", <i>Journal of Biotechnology</i> , <u>98</u> :79-106 (2002) |
| AB | Dayhoff et al., "A Model of Evolutionary Change in Proteins," <i>Atlas of Protein Sequence and Structure</i> , <u>5(3)</u> :345-352 (1978) |
| AC | Diaz et al., "Nomenclature of the Human Interferon Genes," <i>J. Interferon Cytokine Res.</i> , <u>16</u> :179-180 (1996) |
| AD | Drittanti et al., "Effects of 1,25-dihydroxyvitamin D-3 on phospholipid metabolism in chick myoblasts, <i>Biochim Biophys Acta.</i> , <u>962(1)</u> :1-7 (1988) |
| AE | Drittanti et al., "Changes in muscle lipid metabolism induced in vitro by 1,25-dihydroxy-vitamin D-3, <i>Biochim Biophys Acta</i> , <u>918(1)</u> :83-92 (1987) |
| AF | Drittanti et al., "Involvement of the 3',5'-cyclic AMP pathway in the induction of calmodulin synthesis in myoblasts by 1,25(OH)2-vitamin D3," <i>Biochim Biophys Res Commun.</i> , <u>192(2)</u> :886-892 (1993) |
| AG | Drittanti et al., "Modulation of DNA synthesis in cultured muscle cells by 1,25-dihydroxyvitamin D-3," <i>Biochim Biophys Acta.</i> , <u>1014(2)</u> :112-119 (1989) |
| AH | Drittanti et al., "Stimulation of calmodulin synthesis in proliferating myoblasts by 1,25-dihydroxy-vitamin D3," <i>Mol Cell Endocrinol.</i> , <u>74(2)</u> :143-153 (1990) |
| AI | Drittanti et al., "Optimised helper virus-free production of high-quality adeno-associated virus vectors," <i>J Gene Med.</i> , <u>3(1)</u> :59-71 (2001) |
| AJ | Drittanti et al., "Cystic fibrosis: gene therapy or preventive gene transfer?" <i>Gene Ther.</i> , <u>4(10)</u> :1001-1003 (1997) |
| AK | Drittanti et al., "High throughput production, screening and analysis of adeno-associated viral vectors," <i>Gene Ther.</i> , <u>7(11)</u> :924-929 (2000) |
| AL | Du et al., "Efficient transduction of human neurons with an adeno-associated virus vector," <i>Gene Ther</i> <u>3</u> :254-261 (1996) |

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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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|----|---|
| AM | Feng <i>et al.</i> , "Aligning Amino Acid Sequences: Comparison of Commonly Used Methods," <i>J. Mol. Evol.</i> , <u>21</u> :112-125 (1985) |
| AN | Fitch, "An Improved Method of Testing for Evolutionary Homology," <i>J. Mol. Evol.</i> , <u>16</u> (1):9-16 (1966) |
| AO | Fuchs, R.L. and J.D. Astwood, "Allergenicity Assessment of Foods Derived from Genetically Modified Plants", <i>Food Technology</i> , <u>50</u> :83-88 (1996) |
| AP | Gantier <i>et al.</i> , "The L392V mutation of presenilin 1 associated with autosomal dominant early-onset Alzheimer's disease alters the secondary structure of the hydrophilic loop," <i>Neuroreport</i> , <u>10</u> (14):3071-3074 (1999) |
| AQ | Gantier <i>et al.</i> , "The pathogenic L392V mutation of presenilin 1 decreases the affinity to glycogen synthase kinase-3 beta," <i>Neurosci Lett.</i> , <u>283</u> (3):217-220 (2000) |
| AR | Gibrat <i>et al.</i> , "Surprising similarities in structure comparison," <i>Current Opinion in Structural Biology</i> , <u>6</u> :377-385 (1995) |
| AS | Gonnet <i>et al.</i> , "Exhaustive Matching of the Entire Protein Sequence Database," <i>Science</i> , <u>256</u> :1433-1445 (1992) |
| AT | Grantham, "Amino Acid Difference Formula to Help Explain Protein Evolution," <i>Science</i> , <u>185</u> :862-864 (1974) |
| AU | Guyon <i>et al.</i> , "Regulation of acetylcholine receptor alpha subunit variants in human myasthenia gravis. Quantification of steady-state levels of messenger RNA in muscle biopsy using the polymerase chain reaction," <i>J Clin Invest.</i> , <u>94</u> (1):16-24 (1994) |
| AV | Guyon <i>et al.</i> , "Regulation of acetylcholine receptor gene expression in human myasthenia gravis muscles. Evidences for a compensatory mechanism triggered by receptor loss," <i>J Clin Invest.</i> , <u>102</u> (1):249-263 (1998) |
| AW | Henikoff <i>et al.</i> , "Amino acid substitution matrices from protein blocks," <i>Proc. Natl. Acad. Sci. USA</i> , <u>89</u> :10915-10919 (1992) |

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| | |
|----|---|
| AX | Hibbert <i>et al.</i> , "Human Type 1 Interferons Differ Greatly in Their Effects on the Proliferation of Primary B Cells," <i>J. Interferon Cytokine Res.</i> , <u>19</u> :309-318 (1999) |
| AY | Hoedemaekers <i>et al.</i> , "Differential susceptibility of young and old rat neuromuscular junctions to antibody-mediated AChR degradation in experimental autoimmune myasthenia gravis," <i>Ann N Y Acad Sci.</i> , <u>841</u> :550-554 (1998) |
| AZ | Hoedemaekers <i>et al.</i> , "Role of target organ in determining susceptibility to experimental autoimmune myasthenia gravis," <i>J Neuroimmunol.</i> , <u>89</u> (1-2):131-141 (1998) |
| BA | Holm <i>et al.</i> , "Mapping the Protein Universe," <i>Science</i> , <u>273</u> :595-602 (1996) |
| BB | IUPAC-IUB "Commission on Biochemical Nomenclature Abbreviated Nomenclature of Synthetic Polypeptides (Polymerized Amino Acids)," <i>Biochem.</i> , <u>11</u> :942-944 (1972) |
| BC | IUPAC-IUB "Commission on Biochemical Nomenclature A One-Letter Notation for Amino Acid Sequences Tentative Rules", <i>J. Biol. Chem.</i> , <u>243</u> (13):3557-3559 (1968) |
| BD | Johnson <i>et al.</i> , "A Structural Basis for Sequence Comparisons. An Evaluation of Scoring Methodologies," <i>J. Mol. Biol.</i> , <u>233</u> :716-738 (1993) |
| BE | Jones <i>et al.</i> , "The rapid generation of mutation data matrices from protein sequences," <i>Comput. Appl. Biosci.</i> , <u>8</u> :275-282 (1992) |
| BF | Lu, G., "TOP: a new method for protein structure comparisons and similarity searches," <i>J. Appl. Cryst.</i> , <u>33</u> :176-189 (2000) |
| BG | Marrack <i>et al.</i> , "Type I Interferons Keep Activated T Cells Alive," <i>J. Exp. Med.</i> , <u>189</u> :521-530 (1999) |
| BH | Masciovecchio <i>et al.</i> , "The interactivity between the CFTR gene and cystic fibrosis would be limited to the initial phase of the disease," <i>Genet Med.</i> , <u>2</u> (2):124-130 (2000) |

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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|----|--|
| BI | McLachlan, "Tests for Comparing Related Amino-acid Sequences. Cytochrome <i>c</i> and Cytochrome <i>c</i> ₅₅₁ ," <i>J. Mol. Biol.</i> , <u>61</u> :409-424 (1971) |
| BJ | Miyata, "Two Types of Amino Acid Substitutions in Protein Evolution," <i>J. Mol. Evol.</i> , <u>12</u> :219-236 (1979) |
| BK | Morikawa <i>et al.</i> , "Recombinant interferon- α , - β and - γ enhance the proliferative response of human B cells," <i>J. Immunol.</i> , <u>139</u> :761-766 (1987) |
| BL | Moulian <i>et al.</i> , "Respective role of thymus and muscle in autoimmune myasthenia gravis," <i>Ann N Y Acad Sci.</i> , <u>841</u> :397-406 (1998) |
| BM | Murzin <i>et al.</i> , "SCOP: A Structural Classification of Proteins Database for the Investigation of Sequences and Structures," <i>J. Mol. Biol.</i> , <u>247</u> :536-540 (1995) |
| BN | NCBI Nucleotide No. J00207 |
| BO | Orengo <i>et al.</i> , "CATH - a hierarchic classification of protein domain structures," <i>Structure</i> , <u>5</u> (8):1093-1108 (1997) |
| BP | Pestka, <i>et al.</i> , "Interferons and Their Actions," <i>Annu. Rev. Biochem.</i> , <u>56</u> :727-777 (1987) |
| BQ | Piehler <i>et al.</i> , "New Structural and Functional Aspects of the Type I Interferon-Receptor Interaction Revealed by Comprehensive Mutational Analysis of the Binding Interface," <i>J. Biol. Chem.</i> , <u>275</u> :40425-40433 (2000) |
| BR | Poëa <i>et al.</i> , "Modulation of acetylcholine receptor expression in seronegative myasthenia gravis," <i>Ann Neurol.</i> , <u>48</u> (5):696-705 (2000) |
| BS | Poëa <i>et al.</i> , "Expression of ciliary neurotrophic factor receptor in myasthenia gravis," <i>J Neuroimmunol.</i> , <u>120</u> (1-2):180-189 (2001) |
| BT | Rao, "New scoring matrix for amino acid residue exchanges based on residue characteristic physical parameters," <i>J. Pept. Protein Res.</i> , <u>29</u> :276-281 (1987) |

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Title: **RATIONAL DIRECTED PROTEIN EVOLUTION USING TWO-DIMENSIONAL RATIONAL MUTAGENESIS SCANNING**

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| FORM PTO-1449 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT | ATTY. DOCKET NO. 37851-923 | SERIAL NO. 10/658,355 | CONFIRM NO. 3519 |
| | APPLICANT GANTIER et al. | CUSTOMER NO. 24961 | |
| | FILING DATE September 8, 2003 | GROUP 1644 | |

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X+ Derwent English language abstract and/or English translation provided.

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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| | BU | Raux <i>et al.</i> , "The -2 bp deletion in exon 6 of the 'alpha 7-like' nicotinic receptor subunit gene is a risk factor for the P50 sensory gating deficit," <i>Mol Psychiatry</i> , <u>7(9)</u> :1006-1011 (2002) |
| | BV | Raux <i>et al.</i> , "A novel presenilin 1 missense mutation (L153V) segregating with early-onset autosomal dominant Alzheimer's disease," <i>Human Mutat.</i> , Report #134, two pages (2000) |
| | BW | Raux <i>et al.</i> , "Dementia with prominent frontotemporal features associated with L113P presenilin 1 mutation," <i>Neurol.</i> , <u>55(10)</u> :1577-1578 (2000) |
| | BX | Risler <i>et al.</i> , "Amino Acid Substitutions in Structurally Related Proteins A Pattern Recognition Approach," <i>J. Mol. Biol.</i> , <u>204</u> :1019-1029 (1988) |
| | BY | Robert <i>et al.</i> , "Interferon Induces Proliferation In Leukemic And Normal B-Cell Subsets," <i>Hematol. Oncol.</i> , <u>4</u> :113-120 (1986) |
| | BZ | Roisman <i>et al.</i> , "Structure of the interferon-receptor complex determined by distance constraints from double-mutant cycles and flexible docking," <i>Proc. Natl. Acad. Sci. USA</i> , <u>98</u> :13231-13236 (2001) |
| | CA | Sali <i>et al.</i> , "Definition of General Topological Equivalence in Protein Structures," <i>J. Mol. Biol.</i> , <u>212</u> :403-428 (1990) |
| | CB | Sanchez <i>et al.</i> , "Spastic paraplegia and primary adrenal insufficiency: a case of adrenomyeloneuropathy," <i>Medicina (B Aires)</i> , <u>48(3)</u> :290-296 (1988) (Summary in English) |
| | CC | Scheel-Toeller <i>et al.</i> , "Inhibition of T cell apoptosis by IFN- β rapidly reverses nuclear translocation of protein kinase C- δ ," <i>Eur. J. Immunol.</i> , <u>29</u> :2603-2612 (1999) |
| | CD | Shindyalov <i>et al.</i> , "Protein structure alignment by incremental combinatorial extension (CE) of the optimal path," <i>Protein Engineering</i> , <u>11(9)</u> :739-747 (1998) |
| | CE | Smith <i>et al.</i> , "Single-step purification of polypeptides expressed in <i>Escherichia coli</i> as fusions with glutathione S-transferase," <i>Gene</i> , <u>67</u> :31-40 (1988) |

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| CF | Stark <i>et al.</i> , "How cells Respond to Interferons," <i>Annu. Rev. Biochem.</i> , <u>67</u> :227-264 (1998) |
| CG | Wakkach <i>et al.</i> , "Expression of acetylcholine receptor genes in human thymic epithelial cells: implications for myasthenia gravis", <i>J Immunol.</i> , <u>157</u> (8):3752-3760 (1996) |
| CH | Woodley, J.F. "Enzymatic Barriers for GI Peptide and Protein Delivery", <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 11(2&3):61-95 (1994) |

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